EXHIBIT 3

Manufactured for:
GYNECARE WORLDWIDE
A division of ETHICON, INC.
a Johnson & Johnson company
Somerville, New Jersey 08876-0151

Made in Switzerland

EC
Legal Manufacturer
ETHICON, Sàrl
Rue du Puits-Godet 20
CH-2000 Neuchâtel
Switzerland

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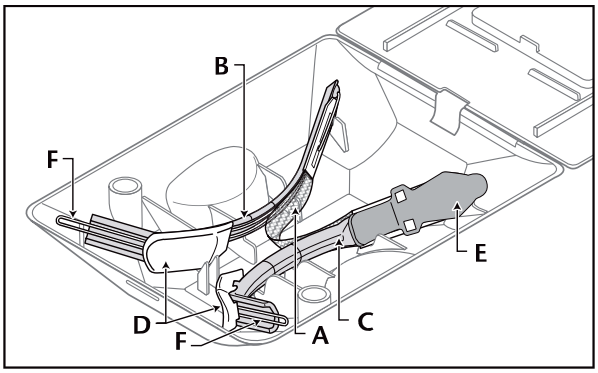

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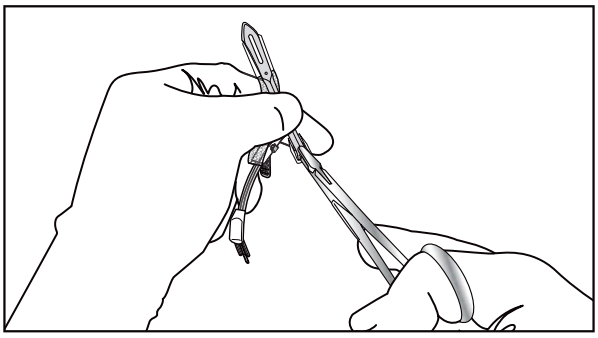

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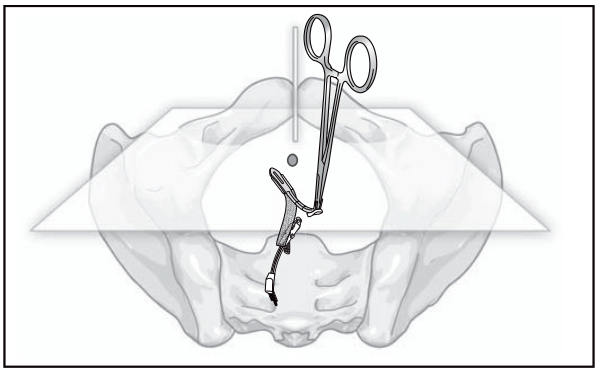

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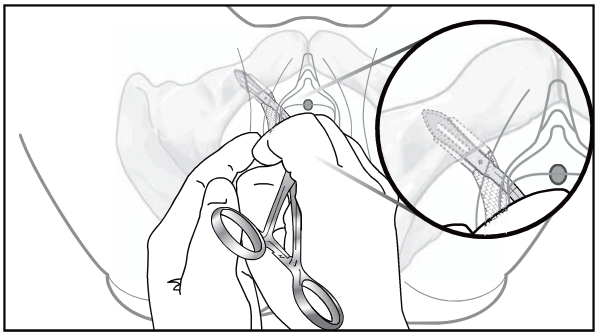

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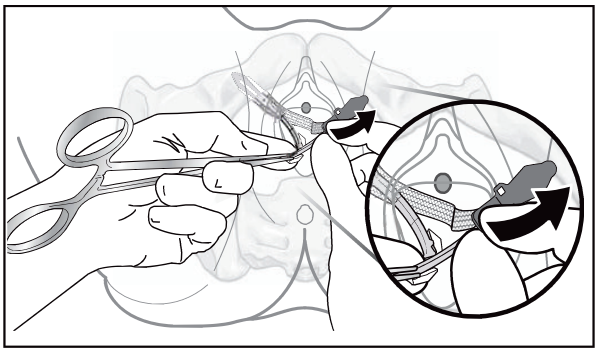

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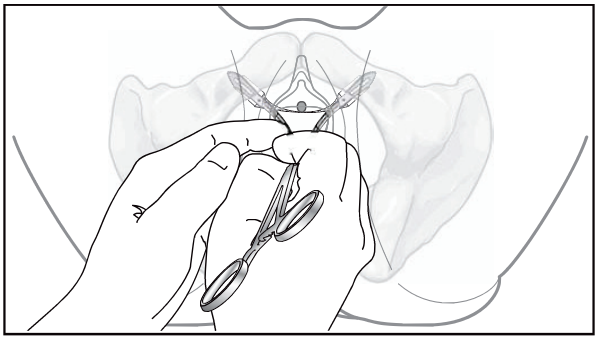

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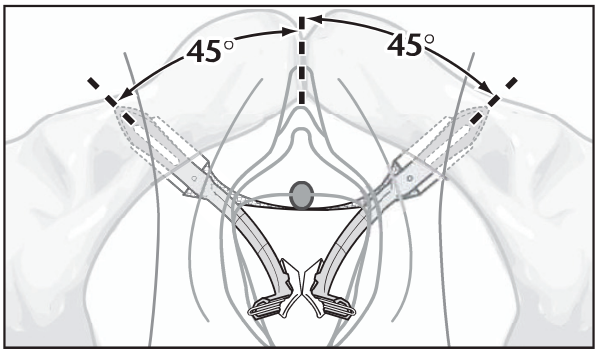

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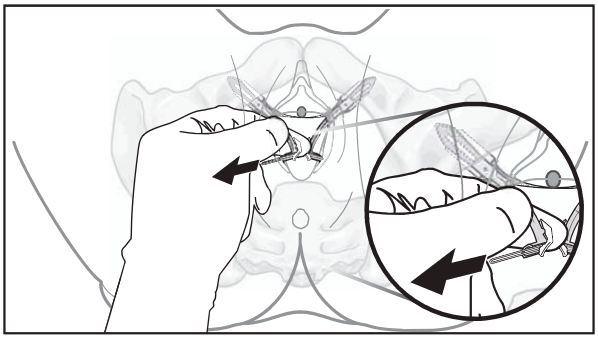

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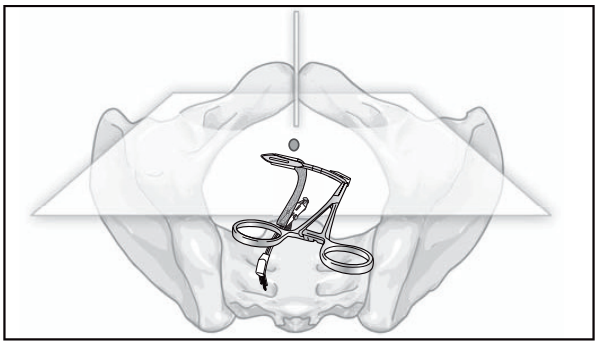

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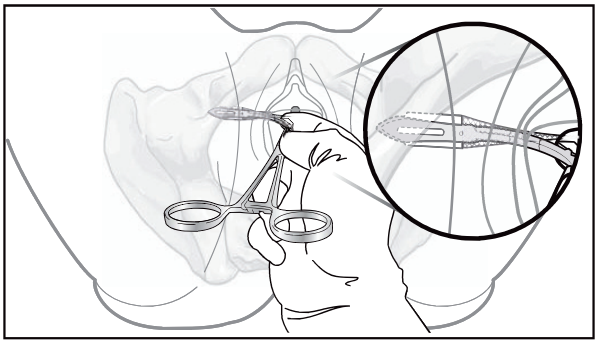

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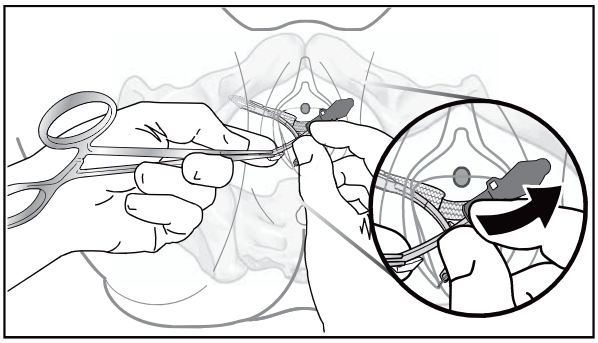

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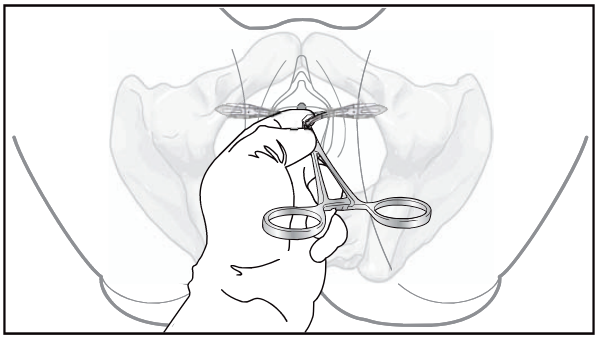

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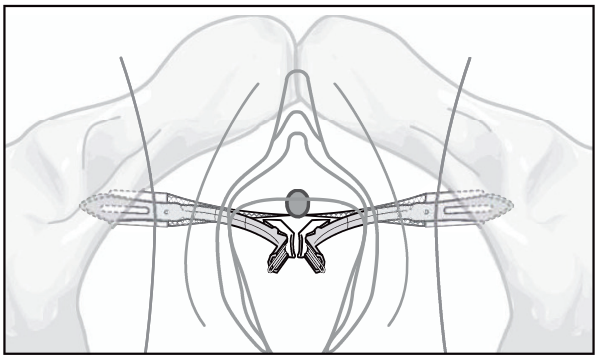

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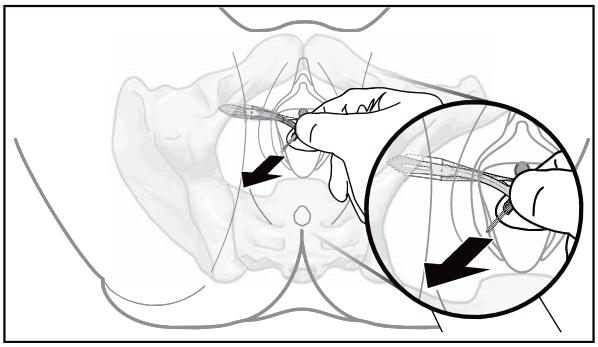

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Gynecare
TVT SECUR® System
Tension-free Support for Incontinence

GYNECARE TVT SECUR* SYSTEM

GYNECARE TVT SECUR* SYSTEM DEVICE;
Hereafter called *Device*

GYNECARE TVT SECUR* SYSTEM INSERTERS;
Hereafter called *Inserter(s)*

Please read all information carefully.
Failure to properly follow instructions may result in improper functioning of the *Device* and may lead to injury.

Important:
This package insert is designed to provide instructions for use of the GYNECARE TVT SECUR* System, including the *Device,* and *Inserters*. It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). Only physicians trained in the surgical treatment of stress urinary incontinence should use the product. These instructions are intended for general use of the product. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

NOTE FOR USE – The GYNECARE TVT SECUR System has been designed such that the procedure can be started on either the patient's left or right side. However for clarity of instructions, the IFU has been written starting the procedure on the patient's right side. If the surgeon's preference is to start on the patient's left side, all procedure steps must be appropriately translated by the surgeon.

DESCRIPTION

The GYNECARE TVT SECUR System is a sterile, single patient use system consisting of:

A – *Device*
B – Un-Protected *Inserter*
C – Protected *Inserter*
D – Finger Pad
E – Protective Cover **(MUST BE REMOVED BEFORE INSERTION)**
F – Release Wire

***Device* (see FIGURE 1)**

The *Device* (item A) is a sterile, single patient use *Device*, consisting of one piece of blue (Phtalocyanine blue, Color index Number 74160) PROLENE* polypropylene mesh (tape) approximately 1.1 cm x 8.0 cm (approx 1/2 x 4 inches) with pieces of fleece made from VICRYL* (polyglactin 910) and PDS*(poly-p-dioxanone) undyed yarn which sandwich the end sections of the mesh. The sandwich is bonded together in a thermal process using two pieces of dyed poly-p-dioxanone film, this film is dyed violet with D&C Violet No. 2 (color index No. 60725)

- PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE polypropylene nonabsorbable surgical suture. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE mesh is knitted by a process that interlinks each fiber junction and which provides for elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.
- The fleece sandwich is a synthetic absorbable composite material made from VICRYL and PDS yarn. The yarn is knitted, processed into a fleece layer; the layers are then sandwiched to the mesh by using two pieces of dyed poly-p-dioxanone film using a thermal process.

The resultant fleece material is of sufficient pore size to allow continuing growth of cells and intrinsic body tissue. The sandwiched fleece ends are mainly undyed, soft, expandable, and pliable. Absorption of sandwiched fleece ends is essentially complete within approximately 90 days. The fleece layers are replaced as connective tissue grows into the mesh. Portions of the PDS yarn/film can be detected up to 180 days post-implantation.

Animal studies show that implantation of PROLENE mesh and the absorbable fleece sandwich material made from VICRYL and PDS yarn elicit a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue, that can grow through the interstices of the mesh system as the fleece portion is being absorbed, thus incorporating the mesh into adjacent tissue. The PROLENE material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

Inserters **(see FIGURE 1)**
The *Inserters* (items B & C) are two curved stainless steel instruments to which a standard needle driver/holder attaches as a stabilizer for controlled insertion. The *Inserters* are provided pre-assembled with the *Device* and are designed to deliver and release the *Device*.

INDICATIONS

The GYNECARE TVT SECUR System is intended for use in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency. This *Device* may be placed in either a "U" or "Hammock" position under the mid-urethra. Placement orientation is per the surgeon's preference.

INSTRUCTIONS FOR USE:

General preparation:

1. The procedure can be carried out under local, regional or general anesthesia.
2. Place the patient in the lithotomy position; maintain the table and patient parallel to the floor.
3. Insert a urethral catheter, and then empty the bladder. **NOTE** – For "U" placement use a Foley catheter and rigid catheter guide. Move the catheter guide to the side of the TVT SECUR Device placement. This will move the urethra and empty bladder to the contralateral side. Repeat the procedure on the other side. After passage of the *Device*, perform cystoscopy to confirm bladder integrity.
   For "Hammock" placement a Foley catheter guide may be used to position the urethra during *Device* placement.
4. Using either forceps or Allis clamps, grasp the vaginal wall at each side of the urethra. Using a small scalpel, make a sagittal incision about 1.0-1.5 cm long starting approximately 1.0 cm from the external urethral meatus. This incision will cover the mid-urethral zone and will allow for subsequent passage of the device. After initiating sharp dissection, continue with a small pair of blunt scissors, making two small paraurethral dissections (approximately 1.0 cm). **NOTE** – These dissections can be made directionally aligned with the surgeon's choice of either the "U" (at 45° from the sagittal midline) or "Hammock" (9 and 3 o'clock positions or parallel to the floor) approaches described below.
5. Remove the internal foil package from the external package and conserve the traceability labels located on the foil package. Then using aseptic technique, open the foil package and remove the plastic tray containing the GYNECARE TVT SECUR System.
6. Open the plastic tray and remove the *Inserters* and *Device* from the plastic tray.

7. Grasp the *Inserter* **without** the protective cover (see FIGURE 1: Item B) using a standard needle driver/holder as shown in FIGURE 2. **NOTE** – Place the tip of the needle driver/holder over the release wire and inside the straight grooved end of the *Inserter*, clamping the two together. Ensure that the connected *Inserter* is inline with the handle of the needle driver/holder. Leave the protective cover on the second *Inserter* until that *Inserter* is used.
8. Based on chosen approach follow either the "U" or "Hammock" position instructions as below.

"U" position: (Reference Figures 3–8)

1. Hold the handle of the selected needle driver/holder in an upright manner for insertion of the *Inserter* and *Device* into the previously dissected paraurethral incision as detailed in the "General preparation" section above on patient's right side, as shown in FIGURE 3. The needle driver/holder and *Inserter* can be held as shown in FIGURE 4 with the index finger on the finger pad (item D of FIGURE 1).
2. Orient the *Inserter* tip to 45° from the sagittal midline (patient's right side) and towards the ipsilateral shoulder. Advance the *Inserter* and contact the lower edge of the pubic bone **(NOTE – if contact is not made within 2 to 3 cm of advancement, STOP and reconfirm proper direction to the pubic bone prior to further insertion).** Once contact is made, lower the handle until it is parallel to the floor as shown in FIGURE 4. While keeping the tip of the *Inserter* in light constant-contact with the pubic bone, position the tip of the *Inserter* inward until the back edge of the pubic bone is reached, and then advance the *Device* upward keeping the *Inserter* tip against the backside of the pubic bone. (**NOTE** – Continuing to lower the handle towards the floor as the *Inserter* is advanced upward may assist in keeping the *Inserter* tip in close contact with the pubic bone.) To minimize the chance of damage to organs, vessels, or other anatomic structures,

keep the tip of the *Device* in close contact with the inferior-posterior aspect of the pubic bone as you insert the *Device* into the connective tissue of the urogenital diaphragm. **NOTE** – When the *Device* is firmly in the connective tissue – STOP. **NOTE** – As a guide, you may use the markings on the *Inserter* to aid in this initial positioning. **NOTE** – Adjustment of the *Device* to achieve tension-free placement should be made by moving the *Inserters* – NOT by pulling on the mesh.

3. Disconnect the needle driver/holder from the first *Inserter*.
4. Connect the needle driver/holder to the second *Inserter* and **REMOVE THE PROTECTIVE COVER (item E of FIGURE 1) from the tip before use, see FIGURE 5 for removal.**
5. Position the handle of the needle driver/holder in an upright manner (see FIGURE 3) for insertion of the *Inserter* and *Device* into the previously dissected paraurethral incision as detailed in the "General preparation" section above on patient's left side. The needle driver/holder and *Inserter* can be held as shown in FIGURE 5 with the index finger on the finger pad (item D of FIGURE 1). **NOTE** – Ensure the mesh is not twisted prior to insertion in order to achieve a flat lie of the mesh under the mid urethra.
6. Orient the *Inserter* tip to 45° from the sagittal midline (patient's left side) and towards the ipsilateral shoulder. Advance the *Inserter* and contact the lower edge of the pubic bone **(NOTE– if contact is not made within 2 to 3 cm of advancement, STOP and reconfirm proper direction to the pubic bone prior to further insertion)**. Once contact is made, lower the handle until it is parallel to the floor as was previously done on the first side. While keeping the tip of the *Inserter* in constant light contact with the pubic bone, position the tip of the *Inserter* inward until the back edge of the pubic bone reached, and then advance the *Device* upward keeping the *Inserter* tip against the backside of the pubic bone, as shown in FIGURE 6. (**NOTE**– Continuing to lower the handle towards the floor as the *Inserter* is advanced upward may assist in keeping the *Inserter* tip in close contact with

the pubic bone.) To minimize the chance of damage to organs, vessels, or other anatomic structures, keep the tip of the *Device* in close contact with the inferior-posterior aspect of the pubic bone as you insert the *Device* into the connective tissue of the urogenital diaphragm. **NOTE** – When the *Device* is firmly in the connective tissue – STOP. **NOTE** – As a guide, you may use the markings on the *Inserters* or the distal end of the *Inserter* to aid in appropriate positioning.

7. Disconnect the needle driver/holder to assess the tension-free mesh placement under the mid urethra. Make final adjustments if needed by reconnecting the needle driver/holder and establishing proper hand position to ensure the *Inserter* tip remains in contact with the pubic bone. Advance or retract the patient's left or right side *Inserter*, depending on the insertion depth of each *Inserter*. **NOTE** – you may use the markings on the *Inserters* or the distal end of the *Inserter* to aid in appropriate positioning. **NOTE** – Adjustment of the *Device* to achieve tension-free placement should be made by moving the *Inserters* – NOT by pulling on the mesh.
8. Assess the positioning of the tension-free tape. (i.e., cough test or other means). **NOTE** – The final position of the *Inserters* should be similar, but they do not need to be symmetrical as shown in FIGURE 7. **NOTE** – If either end of the *Device/Inserter* is placed and then removed and inserted in a second location, the surgeon should ensure that the mesh is securely positioned under the urethra during the final assessment of the tension-free placement.
9. Cystoscopy is **required** with a cystoscope that will provide full visualization of the entire bladder and urethra to assure no inadvertent penetration by the *Inserters* or *Device* of surrounding anatomic structures. If the *Inserter* or *Device* has penetrated any portion of the lower urinary tract, it must be removed and the patient evaluated.

10. When satisfied with the **FINAL** mesh positioning, release one *Inserter* from the *Device* by pulling the release wire (item F of FIGURE 1) while stabilizing the *Inserter* (see FIGURE 8). **NOTE** – The *Device* and *Inserter* cannot be reattached after the release wire is pulled, the release wire **must** be pulled completely to its 'stop' position under the Finger Pad to separate the inserter from the *Device*. To facilitate the implant release, pull the wire using a needle driver/holder, hemostat or forceps.
11. **GENTLY REMOVE** the *Inserter* from the incision after the release wire hits its 'stop'. **A slight twisting motion of the *Inserter* will assist in this maneuver. NOTE** – **DO NOT FORCE** the removal of the *Inserter*, as it may change the implant position or cause the implant end to be removed. If force is needed, reconfirm release wire has been pulled to its 'stop' position and then **GENTLY SLIDE** the *Inserter* out using a slight twisting motion.
12. Ensure **FINAL** mesh position after removal of the first *Inserter*. **NOTE** – If adjustment to the **FINAL** mesh position is needed, adjust the mesh tension with the remaining inserter **BEFORE** pulling the release wire.
13. Repeat step 10 on the other side. (Stabilize the *Inserter* and pull the release wire.)
14. Repeat step 11 on the other side. (**GENTLY REMOVE** the second *Inserter*. **NOTE**: **DO NOT FORCE** the removal of the *Inserter*).
15. Close the vaginal incision.

"Hammock" position: (Reference Figures 9–14)

1. Using the needle driver/holder, insert the *Inserter* and *Device* into the previously dissected paraurethral incision as detailed in the "General preparation" section above on patient's right side (see FIGURE 9). The needle driver/holder and *Inserter* can be held as shown in FIGURE 10 with the index finger on the finger pad (item D of FIGURE 1).

2. Orient the *Inserter* tip at an angle of 45° from the midline, towards the ischiopubic ramus, while holding the needle driver/holder and *Inserter* so that they are parallel to the floor (see FIGURE 10), the *Inserter* tip will be in approximately the 9 o'clock position or parallel to the floor (patient's right side). Advance the *Inserter* and contact the inferior edge of the pubic ramus, and then while maintaining light constant contact with the bone continue to advance the *Device* into the obturator internus muscle in a controlled manner. **(NOTE – if contact with the bone is not made within 3 to 4 cm of advancement, STOP and reconfirm proper direction to the inferior edge of the pubic ramus prior to further insertion)** Keep the tip of *Device* in contact with the bone to minimize the chance of damage to organs, vessels, or other anatomic structures as you advance the *Device* into the obturator internus muscle. **NOTE** – When the *Device* is firmly in the internus muscle – STOP. **NOTE** – You may use the markings on the distal end of the *Inserter* to aid in this initial positioning. **NOTE** – Adjustment of the Device to achieve tension-free placement should be made by moving the *Inserters* – NOT by pulling on the mesh.
3. Disconnect the needle driver/holder from the first *Inserter*.
4. Connect the needle driver/holder to the second *Inserter* and **REMOVE THE PROTECTIVE COVER from the tip (item E of FIGURE 1) before use, see FIGURE 11 for removal.**
5. Using the needle driver/holder, insert the *Inserter* and *Device* into the previously dissected paraurethral incision as detailed in the "General preparation" section above on patient's left side. The needle driver/holder and *Inserter* can be held as shown in FIGURE 12 with the index finger on the finger pad (item D of FIGURE 1). **NOTE** – Ensure the mesh is not twisted prior to insertion on the patient's left side in order to achieve a flat lie of the mesh under the mid urethra.

6. Orient the *Inserter* tip at an angle of 45° from the midline, towards the ischiopubic ramus, while holding the needle driver/holder and *Inserter* so that they are parallel to the floor (see FIGURE 12), the *Inserter* tip will be in approximately the 3 o'clock position (patient's left side). Advance the *Inserter* and contact the inferior edge of the pubic ramus, and then while maintaining light constant contact with the bone continue to advance the *Device* into the obturator internus muscle in a controlled manner. **(NOTE – if contact with the bone is not made within 3 to 4 cm of advancement, STOP and reconfirm proper direction to the inferior edge of the pubic ramus prior to further insertion)** Keep the tip of *Device* in contact with the bone to minimize the chance of damage to organs, vessels, or other anatomic structures as you advance the *Device* into the obturator internus muscle. **NOTE** – When the *Device* is firmly in the obturator internus muscle – STOP. **NOTE** – You may use the markings on the *Inserter* or distal end of the *Inserter* to aid in appropriate positioning. **NOTE** – Adjustment of the *Device* to achieve tension-free placement should be made by moving the *Inserters* – NOT by pulling on the mesh.
7. Disconnect the needle driver/holder to assess the tension-free mesh placement under the mid urethra. Make final adjustments if needed by reconnecting the needle driver/holder and establishing proper hand position to ensure the *Inserter* tip remains in contact with the bone. Advance or retract the patient's left or right side *Inserter*, depending on the insertion depth of each *Inserter*. **NOTE** – You may use the markings on the *Inserter* or the distal end of the *Inserter* to aid in appropriate positioning.
8. Assess the positioning of tension-free tape. (i.e., cough test or other means). **NOTE** – Adjustment of the *Device* to achieve tension-free placement should be made by moving the *Inserters* – NOT by pulling on the mesh. **NOTE** – The final position of the *Inserters* should be

similar but do not need to be symmetrical (see FIGURE 13). **NOTE** – If either end of the *Device/Inserter* is placed and then removed and inserted in a second location, the surgeon should ensure that the mesh is securely fixated under the urethra during the final assessment of the tension-free placement.

9. Cystoscopy may be performed at the discretion of the surgeon.
10. When satisfied with the **FINAL** mesh positioning, release one *Inserter* from the *Device* by pulling the release wire (item F of FIGURE 1) while stabilizing the *Inserter* (see FIGURE 14). **NOTE** – The *Device* and *Inserter* cannot be reattached after the release wire is pulled. The release wire **must** be pulled completely to its 'stop' position in the Finger Pad to separate the Inserter from the *Device*. To facilitate the implant release, pull the wire using a needle driver/holder, hemostat or forceps.
11. **GENTLY REMOVE** the *Inserter* from the incision after the release wire hits its 'stop'. **A slight twisting motion of the *Inserter* will assist in this maneuver. NOTE** – **DO NOT FORCE** the removal of the *Inserter*, as it may change the implant position or cause the implant end to be removed. If force is needed, reconfirm release wire has been pulled to its 'stop' position and then **GENTLY SLIDE** the *Inserter* out using a slight twisting motion.
12. Ensure **FINAL** mesh position after removal of the first *Inserter*. NOTE – If adjustment to the **FINAL** mesh position is needed, adjust the mesh tension with the remaining inserter **BEFORE** pulling the release wire.
13. Repeat step 10 on the other side. (Stabilize the *Inserter* and pull the release wire.)
14. Repeat step 11 on the other side. (**GENTLY REMOVE** the second *Inserter*. **NOTE: DO NOT FORCE** the removal of the *Inserter*).
15. Close the vaginal incision.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- Do not use GYNECARE TVT SECUR System for patients who are on anti-coagulation therapy.
- Do not use GYNECARE TVT SECUR System for patients who have a urinary tract infection.
- Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in the GYNECARE TVT SECUR System before using.
- The GYNECARE TVT SECUR System should be used with care to minimize the chance of damage to large vessels, nerves, bladder and bowel. It is important to pay attention to the specific patient's anatomy while inserting the *Device*.
- Bleeding may occur post-operatively. Observe for any symptoms or signs before releasing the patient from hospital.
- For the **"U" position**, a cystoscopy is required with a cystoscope that will provide full visualization of the entire bladder and urethra to assure no inadvertent penetration of the *Inserter* or *Device*. If the *Inserter* or *Device* has penetrated any portion of the lower urinary tract, it must be removed and the patient evaluated.
- For the **"Hammock" position**, although bladder injury is unlikely to occur with this technique, cystoscopy may be performed at the discretion of the surgeon.
- Ensure that the tape is placed with no tension under the mid-urethra.

- Acceptable surgical practice should be followed for the GYNECARE TVT SECUR System as well as for the management of contaminated or infected wounds.
- Do not perform this procedure if you think the surgical site may be infected or contaminated. If the *Device* is used in contaminated areas it must only be with the understanding that subsequent infection may require its removal.
- Since no clinical information is available about pregnancy following sub-urethral sling procedure with the GYNECARE TVT SECUR System, the patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical information is available about vaginal delivery following a sub-urethral sling procedure with the GYNECARE TVT SECUR System, in case of pregnancy, delivery via cesarean section should be considered.
- Post-operatively, the patient should be advised to refrain from heavy lifting and/or exercise (e.g., cycling, jogging) for at least three to four weeks and to refrain from intercourse for one month. The patient can usually return to other normal activity after one or two weeks.
- The patient should be instructed to contact the surgeon immediately if dysuria, bleeding, or other problems occur.
- As with other incontinence procedures, de novo detrusor instability may occur following a sub-urethral sling procedure utilizing the GYNECARE TVT SECUR System. To minimize this risk, make sure to place the tape as described above.
- Do not affix the PROLENE mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize the *Device* or the system's components. Discard opened, unused *Devices*.
- Prophylactic antibiotics can be administered according to the surgeon's usual practice.

ADVERSE REACTIONS

- Punctures or lacerations or injury to vessels, nerves, bladder, urethra, or bowel may occur during instrument passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies and surgical implants, PROLENE mesh and absorbable materials may potentiate or exacerbate an existing infection.
- Over-correction, i.e., too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.
- Under-correction or incorrect placement may result in incomplete or no relief from urinary incontinence.

HOW SUPPLIED

The GYNECARE TVT SECUR System is provided sterile (ethylene oxide) for single use. Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused *Devices*.

STORAGE

Recommended storage conditions for the GYNECARE TVT SECUR System single use *Device* are below 25°C, away from moisture and direct heat. Do not use after expiry date.

CAUTION: Federal (USA) law restricts this Device to sale by or on the order of a physician.

*Trademark

Symbols Used on Labeling